UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS PO Box 1450 Alexandria, Virginia 22313-1450 www.emplo.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/528,330	02/02/2006	Kim Borch	10312.204-US	5006	
25908 7590 11/12/2909 NOVOZYMES NORTH AMERICA, INC. 500 FIETH AVENUE			EXAM	EXAMINER	
			BADR, HAMID R		
SUITE 1600 NEW YORK, NY 10110		ART UNIT	PAPER NUMBER		
,			1794		
			NOTIFICATION DATE	DELIVERY MODE	
			11/12/2000	EI ECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-NY@novozymes.com

Application No. Applicant(s) 10/528,330 BORCH ET AL. Office Action Summary Examiner Art Unit HAMID R. BADR 1794 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status Responsive to communication(s) filed on RCE 10/21/2009. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 7-24 is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 7-24 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date

Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information-Displaceure-Statement(e) (FTO/SS/08)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

Art Unit: 1794

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/21/2009 has been entered.

Claims 7-24 are being considered on the merits.

Claim Rejections - 35 USC § 112

- The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claims 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 5. Claim 21 is indefinite for "increasing the volume or the crumb color". While increasing the volume of the baked product is a desirable process, increasing the crumb color does not appear to be desirable because usually a lighter, whiter crumb color is an advantage.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

Application/Control Number: 10/528,330

Art Unit: 1794

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- Claims 7-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Negishi et al. (JP 2622563; hereinafter R1) in view of JP 58190346 A (hereinafter R2) and Inoue et al. (US 4,567,046; hereinafter R3)
- R1 discloses the use of lipoxygenase in an amount of 50-500 unit per gram of wheat flour. R1 discloses that such a flour will bring about an increase in the volume of bread and its whiteness. Bread of high quality is produced using the flour (Abstract).
- 3. R1 gives an example of mixing the lipoxygenase and flour so that the flour contains about 100 units of the activity of the enzyme. The prepared flour is then used in bread making by the straight dough method (page 4, machine translation, Example).
- R1 gives the improved characteristics of the baked bread containing lipoxygenase in Table 2, page 5 (machine translation).
- 4. while R1 discloses using wheat lipoxygenase in baking and noting that microbial lipoxygenases were known in the art at the time the invention was made, a microbial lipoxygenase, as presently claimed, could be obviously substituted for wheat lipoxygenase.
- R1 is silent regarding the use of a lipolytic enzyme active on polar lipids in a dough.
- R2 discloses use of lipoxygenase together with lisophosphatidine (LPA) which is enzymatically prepared from soybean lecithin, its salt or the phospholipid mixture having high LPA content in flour which is made into a dough (Abstract)

Art Unit: 1794

7. Lysophosphatidine, as disclosed by R2, is prepared enzymatically from soybean lecithin or a phospholipid mixture. It is noted that the action of a phospholipase is required to hydrolyze lecithin or mixture of phospholipids, therefore, it would be obvious to include phospholipase and its substrate phospholipids into the dough for the generation of lysophosphatidine in situ.

- R2 discloses that the inventive composition improves the specific volume, appearance and the texture of the baked bread.
- R2 is silent regarding the addition of a lipolytic enzyme active on polar lipids in a dough.
- 10. R3 discloses the use of soybean lecithin and emulsifiers in combination with phospholipase A (PL-A) (Col. 3, lines 23-30). It is noted that this enzyme is a lipolytic enzyme active on polar lipids such as phospholipids.
- 11. R3 teaches that the bread improver (containing phospholipase A) can be used in the production of bread by either the sponge dough process or the straight process (col. 3, lines 35-38).
- 12. R3 discloses that phospholipase A (PL-A) is usually added to the ingredients of dough for bread prior to the mixing thereof. Alternatively PL-A may be mixed with either wheat flour or a bakers flour mix containing various auxiliary ingredients. The alternative method has the advantage in that the need for weighing PL-A and adding a suitable amount of PL-A to the ingredient of dough every time the bread-making is done is saved, and a gradual enzymatic reaction is performed during storage (Col. 2, lines 57-65). Limitations of claims 15-17 are met.

Art Unit: 1794

13. R3 discloses that the bread produced according to the inventive process has a large volume and is suitably soft. The bread can also be stored for a prolonged period without undergoing much staling (Col. 4, lines 8-13).

- 14. Given that R1 discloses using lipoxygenase to bring about an increase in the volume of the bread as well as its whiteness and R3 discloses using phospholipids in order to produce bread with large volume that is suitably soft and does not stale for prolonged periods, it would have been obvious to one of ordinary skill in the art to add the lipoxygenase and phospholipids in synergistic amounts to produce bread with optimal volume while still possessing optimal whiteness, softness, and anti-staling properties.
- 15. R1 and R2 are clearly teaching the combination of lipoxygenase and a hydrolyzed phospholipid such as lisophosphotidine (LPA) and the effect of this combination in improving the volume, texture and color of the baked bread. R3 is clearly teaching that a phospholipase can be included in a lecithin containing formulation. It is obvious that the enzymatically prepared LPA that is taught by R2, can be clearly prepared by incorporating a phospholipase into the dough containing lecithin to generate the lysophosphatidine in situ. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to combine a lipoxygenase and a lipolytic enzyme active on polar lipids to bring about synergistic effects on the volume and crumb color of the baked products. Absent any evidence to contrary and based on the combined teachings of the cited references there would be a reasonable

Application/Control Number: 10/528,330

Art Unit: 1794

expectation of success in creating such a combination of enzymes for the purpose of improved bread quality.

- Claims 7-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over
 Strobel et al. (US 3,711,297; hereinafter R4) in view of JP 55153549-A (Abstract, hereinafter R5).
- 17. R4 discloses that activating the natural enzymes of flour by water treatment and incubation at an optimal temperature produces a flour which will result in good volume, texture, crumb color characteristics and a moist quality. (Abstract)
- 18. R4 teaches that the water slurry treatment process allows the naturally occurring wheat flour enzymes, such as lipases, phospholipases and lipoxidases (lipoxygenase) to react with hydrophobic lipid layers surrounding the starch granules. (col. 2, line 65 to col. 3. line13).
- 19. R4 discloses that lipid hydrolysis and oxidation by the natural enzymes produce partial glycerides, free fatty acids, lyso phosphatides and lipoproteins (by the interaction of oxidized lipid with the protein) which are either emulsifiers themselves or are components of the emulsifier systems. All four species aid in stabilizing the cell structure of the batter during baking.
- 20. The action of lipoxidase (lipoxygenase) (oxidation of lipids), lipase (hydrolysis of non-polar lipids) and phospholipase (hydrolysis of polar lipids) in improving the volume, crumb color, and texture and taste of the baked product is discloses by by R4.

Therefore, adding lipoxygenase and lipase or phoshpholipase to the dough or flour, for the same purpose of increased volume, and improved crumb color, would have been Art Unit: 1794

obvious to an artisan. Addition of these enzymes to the dough or flour will ensure enough activity of such enzymes for the desired functional properties of the dough.

- 21. Since microbial lipoxygenase was known in the art, at the time the invention was made, adding a lipoxygenase of microbial origin to the dough would have been obvious to an artisan.
- R4 is silent regarding the synergistic effect of lipoxidase, lipase or phospholipase in the dough.
- 23. R5 discloses a method comprising adding lipoxidase (lipoxygenase) and lipase to unbleached flour. R5 discloses that bread, breadcrumb, noodle etc. having excellent color and flavor can be prepared from unbleached flour.
- 24. R5 further discloses that the combination of lipase and lipoxidase together show synergistic effect.
- 25. It is clearly disclosed by R4 that lipoxidase, lipase and phoshpholipase improve properties of the baked product such as volume, texture, and crumb color. The synergistic effect of the combination of these enzymes, on the properties of the baked products, is also disclosed by R5. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to combine the effect of lipoxygenase, phospholipase or lipase for the same purpose of improving the volume, crumb color, texture, and flavor of baked products. Absent any evidence to contrary and based on the combined teachings of the cited references there would be a reasonable expectation of success in creating such a combination of enzymes for the purpose of improving the quality of baked products.

Art Unit: 1794

Response to Arguments

Applicants' arguments have been thoroughly reviewed. These arguments are not deemed persuasive for the following reasons.

- Applicants argue that while R3 discloses the addition of phospholipase to dough,
 R3 is silent regarding the lipoxygenase.
- a. The inclusion of lipoxygenase is disclosed by both R1 and R2, therefore, R3 does not have to disclose the inclusion of lipoxygegase. The rejection being an obviousness type rejection, the references can not be attacked individually.

 However, note that while R2 and R3 do not disclose all the features of the present claimed invention, R2 and R3 are used as teaching reference, and therefore, it is not necessary for this secondary reference to contain all the features of the presently claimed invention, In re Nievelt, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973), In re Keller 624 F.2d 413, 208 USPQ 871, 881 (CCPA 1981). Rather this reference teaches a certain concept, and in combination with the primary reference, discloses the presently claimed invention.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Art Unit: 1794

Applicants argue that the results obtained by the presently claimed invention are unexpected results i.e. the synergistic effect of the combination of lipoxygenase and lipolytic enzyme.

- a. The synergistic effect of lipoxygenase and lipolytic enzyme was known in the art when the presently claimed invention was made. Please see the new ground of rejection under R5 above.
- b. As set forth in rejections, the disclosures by R1 in view of R2 and R3 are all directed toward the use of lipoxygenase and phospholipase. Further, they all teach the effect of such enzymes on the loaf volume and crumb color of the baked product.
 Therefore their effect in a single composition to be used for the same purpose of volume increase and improvements in the crumb color would be synergistic and obvious.
- Applicants argue that R2 does not teach or suggest the addition of lipolytic enzyme active on polar lipids in the dough.
- a. It should be realized that R2 discloses the addition of lipoxygenase and lisophosphatidine for the purpose of increasing the volume and improving the crumb clolor. This compound is the result of the action of a lipolytic enzyme on phospholipids. Therefore, this teaching has the effect of disclosing the use of a lipolytic enzyme such as phospholipase together with its substrate i.e. a phospholipid like lecithin for generating a lyso phosphatide in situ in the dough.
- Applicants argue that none or R1, R2 or R3 alone or in combination teach or suggest the claimed invention.

Application/Control Number: 10/528,330

Art Unit: 1794

In response, it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [The idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held *prima facie* obvious). (MPEP 2144.06)

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1794

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R Badr Examiner Art Unit 1794

/Keith D. Hendricks/
Supervisory Patent Examiner, Art Unit 1794